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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,308	03/27/2001	Mathieu Hubertus M. Noteborn	4820US	4047

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/819,308	Applicant(s) NOTEBORN ET AL.	
	Examiner Joseph T. Voitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15,16 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,16 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2003, has been entered.

DETAILED ACTION

This application filed March 27, 2001 claims benefit to foreign application 00201108.8 filed March 27, 2000 with European Patent Office.

Applicants' amendment filed August 6, 2003, has been received and entered. Claims 15 and 19 have been amended. Claims 15, 16, 19, 20 and 21 are pending and currently under examination.

Election/Restriction

Applicant's election with traverse of Group VIII, directed to a method of inducing apoptosis in a cell or in a subject comprising administering a polynucleotide set forth in SEQ ID NO: 1 or SEQ ID NO: 9, in Paper No. 9 was acknowledged. Groups VII and VIII were rejoined because it was Examiner indicated that a search of SEQ ID NO: 9 would identify partial

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sequences as encompassed by SEQ ID NO: 1, and thus, would not constitute an undue burden.

Applicant timely traversed the restriction (election) requirement in Paper No. 9. The requirement is still deemed proper and is therefore made FINAL.

Claims 15, 16 and 19-21 are pending and currently under examination as they are drawn to a method of inducing apoptosis in a cell or a subject by administering either SEQ ID NO: 1 or SEQ ID NO: 9.

Applicant is reminded that upon the cancellation of a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The supplemental information disclosure statement filed August 6, 2003, complies with 37 CFR 1.98(a)(2). A copy of the signed and initial PTO-1449 form is included with this action.

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Claim Objections

Claims 15 and 19 objected to because both claims 15 and 19 recite administration of "a host cell transformed with an isolated or recombinant nucleic acid of SEQ ID NO 1 or SEQ ID NO 9, and mixtures thereof" is withdrawn.

Amendments to the claims has obviated the basis of the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have indicated that claim 19 has been amended as indicated in the previous office action obviating the basis of the rejection. See Applicants' amendment, page 4.

Applicants' amendment and argument have been fully considered, but not found persuasive.

It is noted that claim 19 was amended to delete portions directed to non-elected embodiment, however the claims are directed to inducing apoptosis in a subject, encompassing the delivery of a pharmaceutical acceptable carrier for the polynucleotide (as recited in the final line of the method set forth in claim 19). The method is unclear and confusing because the polynucleotide induces apoptosis of the cell in which it is contained, not in any surrounding cells.

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It is unclear how providing the polynucleotide in the context of a pharmaceutical composition of a host cell which at most may undergo apoptosis itself, will provide any form of treatment.

Additionally, it is unclear that even if the host cell is removed from the subject and the cell which is removed is subject to the treatment, how or why replacing said cell transfected with the polynucleotide *ex vivo* would provide any form of treatment of any disease in said subject.

Again, it is noted that the polynucleotide being delivered will induce apoptosis in cells in which is contained, and thus practicing the method will only provide treatment when the polynucleotide is delivered directly to cells which are subject to treatment. The claims are vague and unclear with respect to practicing the instantly claimed method because the methods require the direct administration of the polynucleotide to the cells to induce apoptosis, and it is unclear how the administration of a host cell containing the polynucleotide would provide any form of treatment of a disease wherein enhanced cell proliferation or decreased cell death is observed.

Claims 15 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims encompass the delivery of only isolated SEQ ID NO: 1 or SEQ ID NO: 9 in order to induce apoptosis, however the induction of apoptosis is due to the protein encoded by these sequences. It is unclear how these isolated sequences alone can accomplish the goal of practicing the method because there are no elements associated with the isolated sequences such that they are expressed in a cell. More clearly setting forth that the

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sequences are operatively associated with elements that result in the expression of the encoded protein would obviate the basis of the rejection. Dependent claims 16, 20 and 21 are included in the basis of the rejection because they fail to address how a polynucleotide alone would result in the affect of practicing the method asset forth in the preamble.

Conclusion

The claims are free of the art of record. Claims 15, 16 and 19-21 are free of the art of record however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

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